FDA Asks Court for 18-Month Pause in Key COVID-19 Vaccine Safety Data Cases

The agency was sued after rejecting Freedom of Information Act requests.

The U.S. Food and Drug Administration (FDA) wants an 18-month pause in litigation over its refusal to hand over key safety data on the COVID-19 vaccines.

The request is opposed by two groups that sued the FDA, trying to force the release of the records on possible COVID-19 vaccine side effects following Freedom of Information Act (FOIA) denials.

FDA officials say a federal court should implement the pause because of orders in other cases that require the agency to produce a certain amount of records each month.

After the FDA asked for 75 years to produce documents it analyzed before authorizing the Pfizer-BioNTech COVID-19 vaccine, a federal judge ordered in 2022 the agency to produce the documents in about eight months. The FDA is still producing the records.
In a similar case concerning records on Moderna's COVID-19 vaccine, the FDA is also being required to produce the documents in a few years, rather than the 23.5 years it sought.
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